DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6062-N]

Medicare Program; Updates to the List of Durable Medical Equipment (DME) Specified Covered Items that Require a Face-to Face-Encounter and a Written Order Prior to Delivery

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice updates the Healthcare Common Procedure Coding System (HCPCS) codes on the Durable Medical Equipment (DME) List of Specified Covered Items that require a face-to-face encounter and a written order prior to delivery.

DATES: **[**OFR--insert date of publication in the **Federal Register]**.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Sections 1832, 1834, and 1861 of the Act establish that the provision of durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) is a covered benefit under Part B of the Medicare program.

Section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes us to require, for Specified Covered Items, that payment may only be made

under section 1834(a) of the Act if a physician has communicated to the supplier a written order for the item before delivery of the item. Section 1834(b)(3) of the Act states that section 1834(a)(11) of the Act applies to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of DME. Section 1834(a)(11)(B)(ii) of the Act requires a physician to document that a physician, physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS) has had a face-to-face encounter examination with a beneficiary in the 6 months prior to the written order for certain items of durable medical equipment (DME) or during a different reasonable timeframe determined by the Secretary.

In the Calendar Year (CY) 2013 Physician Fee Schedule (PFS) final rule with comment period, which appeared in the November 16, 2012 **Federal Register** (77 FR 69147), we implemented section 1834(a)(11)(B) of the Act by making revisions to 42 CFR 410.38(g). Among other things, we established a list of Specified Covered Items that require a written order prior to delivery and a face-to-face encounter during the 6 months prior to the written order. (See 42 CFR 410.38(g)(2).) The list of Specified Covered Items contains items that meet at least one of the following three criteria:

- Any item described by a Healthcare Common Procedure Coding System (HCPCS) code for the following types of durable medical equipment:
  - ++ Transcutaneous electrical nerve stimulation (TENS) unit.
  - ++ Rollabout chair.
  - ++ Oxygen and respiratory equipment.
  - ++ Hospital beds and accessories.

++ Traction-cervical.

• Any item of durable medical equipment that appears on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000.

• Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

II. Provisions of the Notice

In the CY 2013 Physician Fee Schedule final rule with comment period (77 FR 69154), we stated that we would publish annually an updated List of Specified Covered Items. (See also 42 CFR 410.38(g)(2).) We specified that we would--(1) add to the list any item of DME (described by an HCPCS code) that in the future appears on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000; and (2) remove from the list any item of DME with a HCPCS code that is no longer covered by Medicare or that has been discontinued.

The purpose of this notice is to provide the annual update to the DME List of Specified Covered Items as stated in the CY 2013 Physician Fee Schedule final rule (77 FR 69154) and as specified in our regulations at § 410.38(g).

This year's update does not reflect any additions because there are no new items that appear on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000. There are also no new HCPCS codes for any of the five types of durable medical equipment listed previously. However, the following two HCPCS codes were removed from the list because they are for items that are no longer payable by Medicare:

HCPCS Code	Short Descriptor
E0457	Chest shell
E0459	Chest wrap

The full updated list is available in the download section of the following CMS website: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html .

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

IV. Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact

analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The CY 2013 expenditures for the two HCPCS codes being removed via this notice was approximately $9,000. Therefore, this notice does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This notice will have no consequential effect on State, local, or tribal governments or on the private sector. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

CMS-6062-N

Dated: March 10, 2015

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE: 4120-01-P

[FR Doc. 2015-07108 Filed: 3/26/2015 08:45 am; Publication Date: 3/27/2015]